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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,694	05/22/2000	Anne Sorensen	Novo-029	3706

23650 7590 09/08/2006

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EXAMINER

HON, SOW FUN

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/577,694		SORENSEN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Sow-Fun Hon		1772	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 63-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/23/06 has been entered.

### ***Response to Amendment***

#### ***Withdrawn Rejections***

2. The 35 U.S.C. 103(a) rejections of claims 63-85 over Kasai (US 4,444,330) as the primary reference, are withdrawn due to Applicant's amendment dated 8/23/06.

#### ***New Rejections***

#### ***Claim Objections***

3. Claim 75 is objected to because of the following informalities: it should depend on claim 63 instead of cancelled claim 1. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claim 75 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the recitation of "heating materials consisting essentially of a butyl based rubber..., and melting a polyolefin" means that the butyl based rubber is only heated, and the polyolefin is melted; or that both the butyl based rubber and the polyolefin are heated, and the polyolefin is melted. Clarification is requested. Furthermore, there is a lack of antecedent basis for the term "stopper material" since claim 1 is canceled.

***Claim Rejections - 35 USC § 103***

5. Claims 63-68, 71-81, 84-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai (US 4,664,275).

Regarding claims 63, 67, Kasai teaches a stopper (column 4, lines 33-35) comprising an injection-mouldable material (can be injection-molded, column 5, lines 47-48), comprising: a blend (mixed by a mixer, column 4, lines 38-40) of a butyl based rubber and a polyolefin (polyethylene, Examples 1-5, column 4, lines 50-70), wherein the butyl based rubber is present in an amount of 30 to 80% by weight (column 1, lines 64-66), which overlaps the claimed range of 70-90%, or 75-87%, by weight; and the polyolefin is present in an amount of 10 to 40% by weight (thermoplastic resin, column

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2, lines 26-29, examples of such thermoplastic resins may include polyethylene, column 2, lines 43-45), which encompasses the claimed range of 30-10%, or 13-25%, by weight; wherein the combination of the butyl based rubber and the polyolefin results in a reduced leakage of substances compared to the leakage of substances from a stopper made from butyl based rubber alone (can maintain a reduced internal pressure for a longer period of time than can a conventional stopper, column 5, lines 39-46, a butyl stopper is conventionally used, column 1, lines 15-18); and wherein the injection-mouldable material further comprises 120 phr or less by weight of filler (column 3, lines 15-20), which overlaps the claimed range of 10% by weight or less; and from 20 phr or less to 5 phr or less of additives (column 3, lines 15-18), which is within the claimed range of 1% by weight or less. Kasai teaches that the prior art stopper comprising butyl based rubber and thermoplastic elastomer is free from the problem encountered with butyl based rubber alone, but still has problems with compression set (column 1, lines 25-35), meeting the claimed proviso that the injection-mouldable material comprises other than a thermoplastic elastomer. Kasai fails to teach any examples of the injection-mouldable material with the claimed combination of weight% ranges of the components.

However, Kasai teaches the injection-mouldable material components with the combination of weight% ranges overlapping the claimed weight% ranges, in the detailed description of preferred embodiments, as described above, used to reduce compression set, provide good gas (column 1, lines 65-68) barrier performance, decrease hardness (column 2, lines 1-2), good moldability (column 2, lines 26-31), and other physical properties, for the purpose of providing a stopper with the desired combination of longer

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internal pressure hold, reduced compression set, good fit and temperature resistance (column 5, lines 40-46).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used the specific composition for the injection-mouldable material with the claimed combination of weight% ranges, for the stopper of Kasai, in order to provide the desired combination of longer pressure hold, reduced compression set, good fit and temperature resistance, as taught by Kasai.

Regarding claims 64-66, Kasai fails to teach the Shore A hardness of the stopper.

However, Kasai teaches that the butyl rubber is blended with at least 10% by weight of polypropylene or polyethylene (column 2, lines 26-31, 40-46), which is varied to provide the desired mouldability (column 2, lines 26-31) balanced with hardness, to the stopper (column 2, line 33). Kasai teaches that the blend is homogenized with heating (mixed at 130°C to 180°C, column 3, lines 20-24), and the stopper is then injection moulded (at 180°C to 220°C, column 3, lines 24-25), wherein since injection moulding requires the blend to be fluid, injection moulding at 220 °C means that the thermoplastic polypropylene or polyethylene is in the melt. Hence the process steps of stopper manufacture, and not just the stopper composition, are similar to those described in Applicant's specification (page 2, lines 25-30). Thus it would have been obvious to one of ordinary skill in the art to have optimized the process of manufacturing the stopper to obtain a hardness of 40-80 Shore A, 45-75 Shore A, or 65-75 Shore A, in order to provide the desired stopper performance, as taught by Kasai.

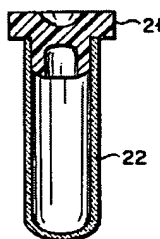
Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have optimized the process of manufacturing the stopper of Kasai, to obtain a hardness of 40-80 Shore A, 45-75 Shore A, or 65-75 Shore A, in order to provide the desired stopper performance, as taught by Kasai.

Regarding claim 68, Kasai teaches that the polyolefin is selected from the group of polyolefins consisting of polypropylene and polyethylene (column 2, lines 40-47).

Regarding claim 71, Kasai teaches that the butyl based rubber is at least partially crosslinked (column 1, lines 65-66).

Regarding claim 72, in Fig. 5 of Kasai, shown below, the stopper (21, column 4, lines 26-31) has a substantially circular cross-section.

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Regarding claims 73-74, Kasai teaches a medical container with non-flexible walls (hard, column 5, lines 42-45). In Fig. 5 of Kasai, shown above, the container 22 comprises a distal and a proximal end, and at least one wall defining an interior space for storing liquid blood (column 5, lines 39-40), and hence alternately liquid medicament since the medical container can also store medicament (drug, column 1, lines 12-13), wherein one of the end portions of the medical container comprises a stopper (21, column 4, lines 26-31). Kasai teaches that the stopper (column 4, lines 33-35)

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comprises an injection-mouldable material (can be injection-molded, column 5, lines 47-48), comprising: a blend (mixed by a mixer, column 4, lines 38-40) of a butyl based rubber and a polyolefin (polyethylene, Examples 1-5, column 4, lines 50-70), wherein the butyl based rubber is present in an amount of 30 to 80% by weight (column 1, lines 64-66), which overlaps the claimed range of 70-90%, by weight; and the polyolefin is present in an amount of 10 to 40% by weight (thermoplastic resin, column 2, lines 26-29, examples of such thermoplastic resins may include polyethylene, column 2, lines 43-45), which encompasses the claimed range of 30-10%, by weight; and wherein the combination of the butyl based rubber and the polyolefin results in a reduced leakage of substances compared to the leakage of substances from a stopper made from butyl based rubber alone (can maintain a reduced internal pressure for a longer period of time than can a conventional stopper, column 5, lines 39-46, a butyl stopper is conventionally used, column 1, lines 15-18); and wherein the injection-mouldable material further comprises 120 phr or less by weight of filler (column 3, lines 15-20), which overlaps the claimed range of 10% by weight or less; and from 20 phr or less to 5 phr or less of additives (column 3, lines 15-18), which is within the claimed range of 1% by weight or less. Kasai teaches that the prior art stopper comprising butyl based rubber and thermoplastic elastomer is free from the problem encountered with butyl based rubber alone, but still has problems with compression set (column 1, lines 25-35), meeting the claimed proviso that the injection-mouldable material comprises other than a thermoplastic elastomer.



It is noted that the recitation of "for storing a liquid medicament" is an intended use one, and is not a positive recitation since a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Kasai fails to teach any examples of the injection-mouldable material with the claimed combination of weight% ranges of the components.

However, Kasai teaches the injection-mouldable material components with the combination of weight% ranges overlapping the claimed weight% ranges, in the detailed description of preferred embodiments, as described above, used to reduce compression set, provide good gas (column 1, lines 65-68) barrier performance, decrease hardness (column 2, lines 1-2), good moldability (column 2, lines 26-31), and other physical properties, for the purpose of providing a stopper with the desired combination of longer internal pressure hold, reduced compression set, good fit and temperature resistance (column 5, lines 40-46).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used the specific composition for the injection-mouldable material with the claimed combination of weight% ranges, for the stopper of Kasai, in order to provide the desired combination of longer pressure hold, reduced compression set, good fit and temperature resistance, as taught by Kasai.

Regarding claim 75, Kasai teaches the process of producing the stopper, comprising the steps of heating and then homogenizing the stopper material (mixed at 130°C to 180°C, column 3, lines 20-24) moulding the stopper by injection moulding (at 180°C to 220°C, column 3, lines 24-25), wherein since injection moulding requires the blend to be fluid, part of the step of injection moulding comprises melting the thermoplastic polyolefin (melt, column 2, lines 39-46), and thus obtaining the stopper. The stopper material consists essentially of a blend of butyl based rubber and a polyolefin, wherein the butyl based rubber is present in an amount of 30 to 80% by weight (abstract), which overlaps the claimed range of 70-90% by weight, wherein fillers are added in an amount of 120 phr additives or less by weight (column 3, lines 18-19), which overlaps the claimed range of less than 10% by weight, and additives are added in an amount from 20 phr or less to 5 phr or less (column 3, lines 15-18), which is within the claimed range of less than 1% by weight.

Regarding claims 77, 80, Kasai teaches a stopper (column 4, lines 33-35) comprising an injection-mouldable material (can be injection-molded, column 5, lines 47-48), consisting essentially of: a blend (mixed by a mixer, column 4, lines 38-40) of a butyl based rubber and a polyolefin (polyethylene, Examples 1-5, column 4, lines 50-70), wherein the butyl based rubber is present in an amount of 30 to 80% by weight (column 1, lines 64-66), which overlaps the claimed range of 70-90%, or 75-87%, by weight; wherein additives are optionally present (can further contain additives, column 3, lines 8-10) in an amount from 20 phr or less to 5 phr or less (column 3, lines 15-18), which is within the claimed range of not exceeding 1% by weight, and fillers are present

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in an amount at the low end of 5% by weight (of an inorganic powder, column 1, lines 49-51) which is within the claimed range of less than 10% by weight. Kasai teaches that the polyolefin is present in an amount of 10 to 40% by weight (thermoplastic resin, column 2, lines 26-29, examples of such thermoplastic resins may include polyethylene, column 2, lines 43-45), which encompasses the claimed range of 13-25%, by weight, and which is the balance of the injection-mouldable material (additives added based on the total weight of the butyl rubber and the thermoplastic resin, column 3, lines 15-16); wherein the combination of the butyl based rubber and the polyolefin results in a reduced leakage of substances compared to the leakage of substances from a stopper made from butyl based rubber alone (can maintain a reduced internal pressure for a longer period of time than can a conventional stopper, column 5, lines 39-46, a butyl stopper is conventionally used, column 1, lines 15-18).

Regarding claims 78-79, Kasai fails to teach the Shore A hardness of the stopper.

However, Kasai teaches that the butyl rubber is blended with at least 10% by weight of polypropylene or polyethylene (column 2, lines 26-31, 40-46), which is varied to provide the desired mouldability (column 2, lines 26-31) balanced with hardness, to the stopper (column 2, line 33). Kasai teaches that the blend is homogenized with heating (mixed at 130°C to 180°C, column 3, lines 20-24), and the stopper is then injection moulded (at 180°C to 220°C, column 3, lines 24-25), wherein since injection moulding requires the blend to be fluid, injection moulding at 220 °C means that the thermoplastic polypropylene or polyethylene is in the melt. Hence the process steps of

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stopper manufacture, and not just the stopper composition, are similar to those described in Applicant's specification (page 2, lines 25-30). Thus it would have been obvious to one of ordinary skill in the art to have optimized the process of manufacturing the stopper to obtain a hardness of 40-80 Shore A, or 65-75 Shore A, in order to provide the desired stopper performance, as taught by Kasai.

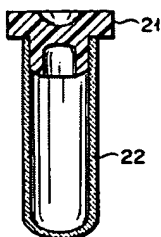
Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have optimized the process of manufacturing the stopper of Kasai, to obtain a hardness of 40-80 Shore A, or 65-75 Shore A, in order to provide the desired stopper performance, as taught by Kasai.

Regarding claim 81, Kasai teaches that the polyolefin is selected from the group of polyolefins consisting of polypropylene and polyethylene (column 2, lines 40-47).

Regarding claim 84, Kasai teaches that the butyl based rubber is at least partially crosslinked (column 1, lines 65-66).

Regarding claim 85, in Fig. 5 of Kasai, shown below, the stopper (21, column 4, lines 26-31) has a substantially circular cross-section.

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6. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai (US 4,664,275) as applied to claims 63-68, 71-81, 84-85 above, and further in view of Esposito (US 3,430,777).

Kasai teaches a medical container for storing a liquid medicament, comprising a distal and a proximal end portion and at least one wall defining an interior space for such liquid medicament, wherein the at least one wall is non-flexible, wherein one of the end portions comprises a stopper comprising an injection-mouldable material comprising a blend of a butyl based rubber and a polyolefin, wherein the butyl based rubber is present in an amount within the range of 70-90% by weight and the polyolefin is present in an amount within the range of 30-10% by weight, wherein the combination of the butyl based rubber and the polyolefin results in a reduced leakage of substances compared to the leakage of substances from a stopper made from a butyl based rubber alone, and wherein the injection-mouldable material further comprises fillers in an amount within the range of 10% by weight or less and additives in an amount within the range of 1% by weight or less, the combined ranges of injection-mouldable material components being obvious to one of ordinary skill in the art, provided that the injection-mouldable material comprises other than a thermoplastic elastomer, as discussed above.

Kasai teaches a process of producing the stopper by the means of injection moulding (column 3, lines 24-25), but fails to teach a process of producing a two-component stopper wherein the stopper is moulded on to a rod by the means of two-component injection moulding.

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However, Esposito teaches that a stopper is moulded (column 2, lines 60-65) on to a rod (push rod 13g integrally formed, column 2, lines 67-68, Fig. 5), for the purpose of providing the stopper with built-in push capability.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have modified the process of producing the stopper by means of injection moulding of Kasai, to provide a process of producing a two-component stopper wherein the stopper is moulded onto a rod by the means of two-component injection molding, in order to provide the stopper with built-in push capability, as taught by Esposito.

7. Claims 69-70, 82-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai (US 4,664,275) as applied to claims 63-68, 71-81, 84-85 above, and further in view of Kasai (US 4,444,330).

K275 (Kasai, US 4,664,275) teaches the stopper comprising the injection-mouldable material comprising butyl based rubber, as discussed above. K275 fails to teach that the butyl based rubber is bromobutyl, which is a halogenated butyl.

However, K330 (Kasai, US 4,444,330) teaches a stopper comprising injection-mouldable material (abstract) comprising butyl based rubber which is a halogenated one (column 1, lines 50-55) such as a bromobutyl rubber (column 2, line 65), for the purpose of utilizing the physical properties provided by the halogenation.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used a halogenated butyl based rubber, such as a bromobutyl rubber, as the butyl based rubber in the stopper of K275, in order to provide

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the stopper with the physical properties provided by the halogenation, as taught by K330.

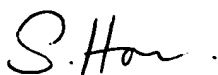
***Response to Arguments***

8. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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